UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL NO. 1456
	)	CIVIL ACTION: 01-CV-12257-PBS
	)	Subcategory Docket: 06-CV-11337-PBS
THIS DOCUMENT RELATES TO	)	Judge Patti B. Saris
U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., et al., No. 06-CV-11337-PBS	)	Magistrate Judge Marianne B. Bowler

ABBOTT LABORATORIES INC.'S REPLY MEMORANDUM IN SUPPORT OF ITS MOTION *IN LIMINE* TO EXCLUDE CERTAIN OPINIONS PROFFERED BY PLAINTIFFS' EXPERT MARK G. DUGGAN, PH.D

Dated: November 2, 2009

Daniel E. Reidy
James R. Daly
Jason G. Winchester
Brian J. Murray
JONES DAY
77 West Wacker Drive, Suite 3500
Chicago, Illinois 60601
Telephone: (312) 782-3939
Facsimile: (312) 782-8585

R. Christopher Cook
David S. Torborg
JONES DAY
51 Louisiana Avenue, N.W.
Washington, D.C. 20001-2113
Telephone: (202) 879-3939
Facsimile: (202) 626-1700

Counsel for Defendant Abbott Laboratories Inc.

DOJ's response to Abbott's motion *in limine* ignores the overarching issues that render Dr. Duggan's extrapolation methodologies unacceptable in theory and unreliable in application. And DOJ's claim that "every last cent of Dr. Duggan's damage calculations is backed by reliable, verifiable claims data," (G. Br. at 1), is false. The relevant data here would be evidence showing how, if at all, reported prices *actually impacted* payments. For Medicaid, it would be detailed claims data from the states. For Medicare, it would be the pricing arrays. Duggan's calculations are not backed up "to every last cent" because DOJ did not preserve the detailed claims data and pricing arrays while this case languished under seal. In the end, Duggan's calculations are backed up only by a patchwork of claims data and arrays from 10 states and a handful of Medicare contractors. Duggan's calculations for the remaining states, contractors, and missing time periods – fully $57 million of the $107 million total – are based on extrapolations. That amount is untethered to data showing how reported prices actually influenced payments.

Extrapolation may be permissible, but only when supported by accepted methodologies. The root problem with Duggan's analysis is his admitted failure to use representative samples of the allegedly false claims at issue. Instead, Duggan resorted to biased, "convenience samples" focused on high-expenditure states and Medicare contractors. Abbott's brief demonstrated that Duggan's failure to adhere to statistical standards, coupled with significant variability in how states and carriers paid for the Subject Drugs, led to absurd results akin to what this Court saw in *Loughren v. UnumProvident Corp.*, 604 F. Supp. 2d 259, 264 (D. Mass. 2009). (Abt. Br. at 20-23.) DOJ does not dispute that Duggan's extrapolations lead to clearly erroneous results. Yet, DOJ suggests – without empirical, logical, or legal support – that it "all comes out in the wash," and that the problems with Duggan's work should be deferred until cross-examination. The Court should reject that plea, as the "*Daubert-Kuhmo* canon teach[es] that the critical issue is the soundness of [the expert's] methodology, for only such soundness provides a reasonable

assurance that the GIGO ('garbage in, garbage out') hazard has been avoided." *Alexian Bros. Health Providers Ass'n, Inc. v. Humana Health Plan, Inc.*, 608 F. Supp. 2d 1018, 1027 (N.D. Ill. 2009). A *Daubert* challenge is the appropriate way to assess the reliability of an expert's methodology. This is particularly true here, where DOJ seeks treble damages and penalties on every claim for which Duggan, often erroneously, extrapolates a "difference."

No court has allowed the sort of methods used here. This Court should not be the first.

ARGUMENT

I. DUGGAN'S EXTRAPOLATIONS ARE NOT BASED ON REPRESENTATIVE SAMPLES AND ARE INCONSISTENT WITH GOVERNING STANDARDS.

Courts permitting extrapolation have universally required the use of a statistically valid, representative sample. *See Loughren*, 604 F. Supp. 2d at 261 ("extrapolation is a reasonable method . . . so long as the statistical methodology is appropriate") (citing cases). Duggan's purported "samples" of 5.6 million claims (2 million for Medicaid, 3.6 million for Medicare) are not "samples" of anything. A sample is a "*subset* of the population that is used to gain information about *the entire population*," or a "method of selecting a *fraction of the population* in a way that the selected sample *represents the population*." *Utah v. Evans*, 536 U.S. 452, 467-68 (2002) (emphasis added) (citing G. Henry, *Practical Sampling* 11 (1990); P. Sukhatme, *Sampling Theory of Surveys with Applications* (1954)). Duggan admits that his 5.6 million claims are not "subsets" of the entire population of allegedly false claims. Rather, they are the *entirety* of the claims data and arrays for certain states and carriers at certain times.

Duggan's "samples" are not valid because they are not drawn from "the population [of] the whole class of units that are of interest" – claims from *all* states, *all* carriers, and *all* time periods – such that each claim had a "known, nonzero probability of being chosen." *Reference Manual on Scientific Evidence* at 90, 100. Due to the variation in how states and carriers paid for the Subject Drugs, "samples" that omit claims from 39 states and scores of carriers entirely, and

omit years of claims from others, are not representative. *See id.* at 90 ("[T]he population is the whole class of units that are of interest; the sample is a set of units chosen for detailed study. Inferences from the part to the whole are justified only when the sample is representative."). For much of the period, Duggan's extrapolations rely on claims from fewer than 5 states (out of 49) and 5 Part B carriers (out of over 90). In statistic jargon, his "samples" are under-inclusive.

DOJ's citation to page 244 of the *Reference Manual*, (G. Br. at 15), is inapposite. Page 244 concerns the irrelevant context of consumer *surveys*. Even there, the *Reference Manual* and case law recognize that issues associated with using non-representative samples may render the survey results inadmissible. *See id.* at 231, 241-43; *Chavez v. IBP, Inc.*, No. CV-01-5093-RHW, 2004 WL 5520002, at * 8-9 (E.D. Wash. Dec. 8, 2004) (excluding survey not based on random, probability sample). By contrast, the standards cited by Abbott, such as CMS's own Transmittal B-03-022, *Use of Statistical Sampling for Overpayment Estimation When Performing Administrative Reviews of Part B Claims*, are directly on point. DOJ admits that Duggan's extrapolations do not meet the standards articulated by CMS, and instead urges the Court simply to ignore CMS's own guidance on the topic. This the Court should not do, particularly in a case where the Government seeks to treble any damages computed through extrapolation.[1]

The three papers cited on page 17 of the Government's brief – all done outside of litigation – bear no resemblance to Duggan's work here. None of these studies extrapolated findings from one subset of a population to different subsets of the population known to have widely varying characteristics on the key parameters at issue. And, there, the authors took steps to assure the comparability of the sample and the extrapolated population, or to control for

[1] *See* Breckinridge L. Wilcox & Jefferson M. Gray, *Extrapolation of Damages and Penalties in Fraud Cases: A Slippery Slope in FCA Actions*, Business Crimes Bulletin (Dec. 2000) ("[T]he FCA's provisions for multiple damages and penalties mean that the financial impact of any claims erroneously treated as improper under the extrapolation will be greatly magnified.").

variances.[2] Duggan did not do that here. He did not control for variables – *e.g.*, the impact of MACs and differences in dispensing fees – between the sample and extrapolated populations.

At bottom, the methodologies challenged here involve the extrapolation of findings from a non-random, non-representative set of claims to another collection of claims processed either by a different set of states and carriers or at different times. Neither Abbott nor DOJ has identified a single case allowing an expert to present the sort of extrapolations employed here.

II. VARIABILITY IN HOW STATES AND CARRIERS PAID FOR THE SUBJECT DRUGS UNDERSCORES THE NEED FOR REPRESENTATIVE SAMPLES.

The problems with Duggan's extrapolations are more than academic. This case concerns four Abbott generic drugs typically administered intravenously, often after being compounded with other drugs. The significant variability in how states and carriers paid providers for dispensing these products demands the use of representative samples in any extrapolation.

Medicaid. As stated in OIG's report *Variation in State Medicaid Drug Prices*, "states' prices vary most for non-innovator multiple source drugs." (Abt. SOF ¶ 136.) Abbott's opening brief and accompanying statement of facts demonstrated wide variability in how state Medicaid programs paid for the Subject Drugs. (*See* Abt. Br. at 17, 20-25; Abt. SOF ¶¶ 21-22, 30, 36-37, 99, 103, 105, 108, 125, 137, 139, 141.) Consistent with OIG's findings, the claims data that was produced by the states here shows the type of variability for the Subject Drugs that OIG found for generic drugs in general. For example, Exhibits D through J, attached, contain claims data for 7 individual claims paid during 2000 by 7 different states for NDC 00074613802 (sodium

[2] *See* Jonathan Gruber and David Rodriguez, *How Much Uncompensated Care to Doctors Provide?*, Journal of Health Economics 26 (2007), at 9-11, 22-26 (Ex. A); Bruce D. Meyer, *Unemployment Ins. and Unemployment Spells*, Econometrica Vol. 58 (July 1990), at 765-71 (Ex. B); Kathleen Adams, Jonathan Gruber, and Joseph Newhouse, *Physician Fee Policy and Medicaid Program Costs*, The Journal of Human Resources Vol. 32 (Fall 1997), at 617-22 (Ex. C).

chloride 0.9% irrigation). As shown in the following chart, there was significant variability in per-unit ingredient payment amounts.[3]

	States in Duggan's "Sample"				States Not in Duggan's "Sample"		
State	**KY**	**IL**	**MI**	**MO**	**AR**	**OH**	**TX**
Payment per unit	5.06¢	4.87¢	1.29¢	5.03¢	1.33¢	0.63¢	2.28¢

This type of variability is fatal to Duggan's extrapolations.

DOJ exaggerates when it states that Duggan performed "numerous analyses to substantiate that the claims in his sample population were a reliable basis for extrapolation." (G. Br. at 8.) Most of these "analyses" are irrelevant to pinpointing the type of differences shown above.[4] That leaves just two "analyses": (1) the alleged "stability of the fraud ratio across the 10 states" and (2) Duggan's purported comparison of an average "per-claim" paid amount in the 10 states for which he examined data and the 39 states where he did not. Neither excuses the need for a representative sample or renders Duggan's conclusions reliable.

To the contrary, the alleged stability of the "fraud ratio" demonstrates selection bias, not reliability. The alleged stability of the "fraud ratio" is precisely *because* Duggan included high-expenditure states in his 10-state "sample," and excluded states that placed MACs on the Subject Drugs. (Abt. Br. at 14-18.) Had Duggan included the latter (*e.g.*, Texas, Arkansas, Maryland, and Ohio) in the "sample," the "fraud ratio" would not have been stable at all. Indeed, Duggan

[3] Each of the 7 claims attached is representative of the per-unit reimbursement the state paid for NDC 00074613802 during 2000; none the 7 claims was reimbursed on the basis of billed charges.

[4] The irrelevant "analyses" include DOJ's observations that states are "subject to the same federal regulations," that states "used published prices when adjudicating claims," and that the "reimbursement scaling factors for the prices are on average similar between the two groups." (G. Br. at 9.) The same can be said for the generic products studied in OIG's 2004 study, yet state prices still were all over the map. As OIG noted: "Even States with the same formula for estimating pharmacy acquisition demonstrated variation in their average annual reimbursement prices." (Abt. SOF ¶ 136.)

observed in his initial report (before he removed Ohio) that the "fraud ratio" decreased substantially when states used MACs. (Duggan 6/19/08 Rpt. at 67: "It is worth noting that the ratio of DIFFERENCE to the total amount of Medicaid spending is substantially lower in Ohio than in the preceding states. This is largely driven by the state's more frequent use of MACs."). This type of selection bias is precisely why courts require valid samples. (Abt. Br. at 14, 18.)

DOJ's reliance on Duggan's comparison of per-claim paid amounts between the 10 and 39 states, (G. Br. at 9), also falls short. Initially, Duggan's comparison covered only the 1999-2001 time period, less than one-third of the 1991-2001 damage period. Moreover, DOJ misstates what Duggan actually did. Duggan's comparison *included Ohio* in the "10 states" (such that it really was 11 states). (Abt. SOF ¶ 112.) Ohio had the lowest per-claim spending in this group, inasmuch as it placed MACs on the Subject Drugs. As a result, including Ohio in his comparison lowered the per-claim spending for the 11 states, allowing Duggan to conclude that per-claim spending was higher in the extrapolated states for 24 of the 44 NDCs. (*Id.*) But Duggan did not re-perform the analysis after he dropped Ohio. (*Id.*) Had he done so, the per-claim spending in the 10 states would have been higher. (*Id.*) DOJ has no basis to rely on this comparison. (*Id.*) Finally, perhaps most importantly, Duggan himself acknowledged the shortfalls in his simple comparison, testifying that many variables – apart from any consistency in per-unit drug payments – factor into the states' per-claim spending figures. (Abt. Br. at 20.)

One of those variables – dispensing fees – is critical here. At least 15 of the 39 states used enhanced dispensing fees for intravenous and compounded drugs, compared to just 2 of the 10 "sample" states (and Michigan hardly counts because Duggan had only 5 out of 44 quarters of data). (*Id.* at 24.) Although its Rule 56.1 response agrees with these figures, (*see* Dkt. No. 316 ¶ 141), DOJ disregards its own consulting expert's findings and contends disingenuously that only 4 of the 39 states had higher dispensing fees. (G. Br. at 22-23.) DOJ is wrong.

Duggan in no way controlled for this critical issue. Building off of DOJ's example (at 22) illustrates the problem. In DOJ's example, changing the drug payment from $10 to $2, while keeping the $4 dispensing fee stable, results in a "fraud ratio" of 57% ($8 over $14). Although DOJ gushes over the alleged reasonableness of this "fraud ratio," the practical results show otherwise. To calculate his "difference," Duggan applies this "fraud ratio" to the aggregate expenditures of the 39 no-data states, figures that *include dispensing fees*. Because the dispensing fee-to-ingredient cost ratio is higher in the 39 states, Duggan overstates damages. For example, Nevada paid a dispensing fee of $16.80 for the first dose of intravenous medication. (Abt. SOF ¶ 141.) Using DOJ's example, assume Nevada paid $10 in ingredient cost and a $16.80 dispensing fee on an intravenous drug, for a total of $26.80. Application of Duggan's 57% "fraud ratio" to the $26.80 total payment computes a "difference" of $15.27 – *$5.27 more than Nevada paid for the drug in the first place*. So, while Duggan purports to calculate only the "difference" between what the state paid for the drug, his use of aggregate expenditure data without accounting for significantly varying dispensing fees renders the entire exercise unreliable. Had DOJ preserved a representative sample of claims from all states, this issue could have been identified and controlled for at the outset.[5]

Finally, this Court has held that defendants are not liable on claims that were paid on the basis of a MAC, where there is no link to defendant's prices. (*See* Dkt. No. 6186 at 12.) Duggan ignores this holding, calculating "differences" on MAC-based payments without any link to reported prices. For this reason as well, Duggan's Medicaid extrapolations should be excluded.

[5] Nor does DOJ respond to the problems with Duggan's within-state extrapolations. Lacking the necessary data, Duggan did not evaluate whether the existence and levels of MACs and the frequency with which drugs were paid on the basis of U&C changed over time. The data show a significant decline in the percentage of U&C-based payments over time. (Abt. Br. at 25-26.) Extrapolating from a period with a higher percentage of EAC-based payments to a period with a lower percentage of such payments would overstate the "difference" in the extrapolated period. (*Id.*)

Medicare. The parties agree that significant variability exists across the Part B carriers in the mix of NDCs included in the arrays used for J-Codes at issue. (G. Br. at 25.) Due to this variability, just showing how the median AWP would change with lower Abbott AWPs for a set of array-producing carriers (the "sample") does not reasonably predict the impact of revised Abbott AWPs on claims paid by carriers that did not produce arrays.

Duggan's purported "sample" consists of 3.6 million claims paid by Medicare contractors for which DOJ secured pricing arrays. As in *United States v. Skodnek*, the "sample" was not "done according to the usual statistical formalities," but instead was a "convenience sample garnered by a unit whose purpose is to investigate fraud." 933 F. Supp. 1108, 1115-18 (D. Mass. 1996). DOJ has allowed no visibility into how the "sample" was collected, having asserted privilege over the array-gathering process. Furthermore, Duggan's sample is not nearly as comprehensive as DOJ suggests. DOJ contends that Duggan had the arrays "used by" 21 Part B carriers, (G. Br. at 5, 10), suggesting that his "sample" consists of actual arrays from 21 different carriers. In fact, Duggan had unique arrays for *just four* (Cigna, WPS, Metra Health, and Florida BS) of over 90 Part B carriers, as 17 of the 21 Part B carriers allegedly used the WPS arrays. (This motion does not seek to exclude Duggan's "difference" opinion relating to the 17 carriers.)

DOJ's contentions regarding the comparability of the Part B carriers ignore the relevant issue: the impact that using Duggan's revised AWPs has on the median AWP calculation. That impact is driven by the mix of NDCs in the arrays, as the variability in the carriers' arrays leads to very different results. (Abt. Br. at 27-28.) DOJ's contention that payments across the Part B carriers were "quite similar," (G. Br. at 24), tells us nothing about the impact of using revised AWPs on the median. Indeed, the comparison of two carriers' arrays for J7050 (the largest damage J-Code) discussed in Abbott's opening brief and Duggan's report proves this. While the carriers paid "similar" amounts ($10.69 vs. $11.15), Duggan's revised arrays yield very different

"fraud ratios" (14.8% decrease vs. 47.9% decrease). (Abt. Br. at 27-28.) Because he lacks arrays from most carriers, Duggan simply could *not* have "analyzed the data for the two groups and showed that there were only minor differences between the carriers." (G. Br. at 25.)

III. DUGGAN'S EXTRAPOLATION OPINIONS SHOULD BE EXCLUDED.

DOJ does not dispute the examples cited in Abbott's brief which prove the unreliability of Duggan's extrapolations, including situations where Duggan's approach leads to states paying *negative* amounts in ingredient reimbursement. (Abt. Br. at 20-23.) Those examples are not "cherry-picked," but rather are symptomatic of why Duggan's failure to use representative samples render his extrapolations unreliable.

Simply put, Duggan did *not* "scrupulously note differences in the populations and either decline to extrapolate or extrapolate only after making suitable adjustments to scale the extrapolation down (and never up)." (G. Br. at 6.) He did *not* adjust his extrapolation to consider state MACs. He did *not* adjust his extrapolation to consider higher dispensing fees in the 39 states. He did *nothing* to adjust his across-state Medicaid extrapolations or decline to extrapolate across the states, and any adjustments he made for Medicare are speculative at best.

DOJ responds to these problems by essentially claiming that it all comes out in the wash:

> Dr. Duggan evaluated the appropriateness of an extrapolation to 38 states *in toto* and implemented his extrapolation in that fashion. Abbott's solo state examples warp Dr. Duggan's approach and fail to demonstrate that his approach is not accurate when implemented across the board.

(G. Br. at 21.) But Plaintiffs – who have the burden here – have not provided any empirical evidence to show that Duggan's approach is, in fact, "accurate when implemented across the board." Indeed, because the relevant data has been lost, neither DOJ, Duggan, nor Abbott's experts can quantify the errors that result from the flaws in Duggan's methodologies.

Remarkably, DOJ blames Abbott for somehow making calculations more difficult and criticizes Abbott's experts for failing to quantify Duggan's errors. (G. Br. at 13, 23, 28-30.) In

truth, DOJ resorts to Duggan's extrapolations because it spoliated the data necessary to make less convoluted calculations (and for Abbott's experts to quantify the errors). The Court should reject DOJ's attempt to "fill the gaps" in the spoliated evidence through expert testimony, not allow leniency. *See United Med. Supply Co. v. United States*, 77 Fed. Cl. 257, 275 (2007) (rejecting expert testimony designed to fill "gaps" in evidence created by Government spoliation).

The burden to establish the reliability of Duggan's testimony rests squarely on Plaintiffs, not on Abbott or its experts. *See Loughren*, 604 F. Supp. 2d at 264; *Alexian Bros.*, 608 F. Supp. 2d at 1027; *Reynolds v. Giuliani*, 118 F. Supp. 2d 352, 367 (S.D.N.Y. 2000) ("The City defendants, as the proponents of the audit, bear the burden of assuring that the results lack statistical bias. In this Court's view, they have not done so. Once plaintiffs had thoroughly undermined the structuring underpinnings of the Reynolds Audit, they were not required to identify the direction in which it would topple."). This is particularly true here, where Duggan ignored well-established standards governing the use of extrapolation, and did not present this Court with any sort of confidence interval to assess the reliability of his extrapolations.

As is often the case when a party proffers unsound expert testimony, DOJ asks the Court to ignore the fundamental shortcomings of Duggan's methodologies and leave those issues for cross-examination at trial. Even without the extrapolated aspects of Duggan's opinions, cross-examination of Duggan will be extensive and complicated. It is not the jury's role to learn and decipher the complex statistical issues that surround Duggan's extrapolations. They will have enough to do in this complicated trial. The Court's "vigilant exercise" of its "gate-keeper role is critical," and the cracks in the structural underpinnings of Duggan's extrapolation methodologies are precisely why the Court should exclude the proffered testimony. *Loughren*, 604 F. Supp. 2d at 264 ("An expert's methodology is the 'central focus of a *Daubert* inquiry.'").

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Respectfully submitted,

/s/ R. Christopher Cook
Daniel E. Reidy
James R. Daly
Jason G. Winchester
Brian J. Murray
JONES DAY
77 West Wacker Drive, Suite 3500
Chicago, Illinois 60601
Telephone: (312) 782-3939
Facsimile: (312) 782-8585

R. Christopher Cook
David S. Torborg
JONES DAY
51 Louisiana Avenue, N.W.
Washington, D.C. 20001-2113
Telephone: (202) 879-3939
Facsimile: (202) 626-1700

Counsel for Defendant Abbott Laboratories Inc.

CERTIFICATE OF SERVICE

I, David S. Torborg, an attorney, hereby certify that I caused a true and correct copy of the foregoing to be served on all counsel of record electronically by causing same to be posted via LexisNexis, this 2nd day of November, 2009.

/s/ David S. Torborg
David S. Torborg